

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Serial No. 10/635,919
Confirmation No. 8849

Group Art Unit 3733
Examiner: Michael B. Priddy

Title: Implant Plate and Method for the Manufacture Thereof

I hereby certify that this correspondence is being transmitted to the United States Patent & Trademark Office via electronic submission or facsimile on the date indicated below:

<u>12/06/2007</u>	<u>/Pamela Gerik/</u>
Date	Pamela Gerik

APPEAL BRIEF

Sir/Madam:

Further to the Notice of Appeal filed October 9, 2007, Appellant presents this Appeal Brief. The Notice of Appeal was filed following receipt of a final Office Action mailed July 9, 2007. Appellant hereby appeals to the Board of Patent Appeals and Interferences from the final rejection of claims 29-31 and respectfully requests that this appeal be considered by the Board.

I. REAL PARTY IN INTEREST

The subject application is owned by the inventors, Claudius Zeiler and Ernst Wiedemann.

II. RELATED APPEALS AND INTERFERENCES

No appeals, interferences, or judicial proceedings are known which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 17-19, 21, 22, and 29-31 are pending in the captioned case. Claims 1-16, 20, and 23-28 are canceled. Claims 17-19, 21, and 22 are withdrawn. Claims 29-31 stand rejected and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments to the claims were filed subsequent to their final rejection. Therefore, the Appendix hereto reflects the current state of the claims 29-31 as on appeal. However, Applicants note a typographical error in claim 29, line 26, “round hood” should be “round hook.” This correction is marked in the claims appended hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 29 describes an implant plate for stabilizing a fracture of at least one of an upper arm head or a proximal upper arm (Specification -- pg. 1, lines 12-18), comprising: a plate member shaped to bear against a surface of an upper arm head bone and a surface of a proximal upper arm bone (Specification -- pg. 3, lines 24-32; pg. 9, lines 1-12; Figs. 1A-1B); holes for bone screws on the plate member for fixing the plate member to the bone surfaces (Specification -- pg. 4, lines 1-5; pg. 6, lines 19-25); at least one receiving member for flexible cerclage wires or suture material wound around fractured bone parts, allowing a passage and tightening of the wire cerclage or suture material after the plate member has been secured to the bone surfaces (Specification -- pg. 6, lines 3-5; pg. 12, lines 1-3); wherein the plate member is a one-piece plate cut or punched from a flat metallic strip material having a substantially uniform thickness of 0.5 to 6.5 mm to have plate edges defining a head-end portion and a shaft-end portion adjacent to the head-end portion along a longitudinal direction, with the shaft-end portion being narrower along a lateral direction than the head-end portion, and bent to have a slight curvature to form a longitudinal channel, and to allow a bone-facing surface of the head-end portion and a bone-facing surface of the shaft-end portion to bear against the outer surfaces of the upper arm head bone and the proximal upper arm bone (Specification -- pg. 4, lines 1-12;

pg. 12, lines 3-10; pg. 13, lines 1-3); wherein the holes for bone screws are located on the head-end portion and the shaft-end portion (Specification -- pg. 5, lines 24-26; pg. 12, lines 20-24); wherein the at least one wire cerclage or suture material receiving member is disposed on a head-end portion surface which is opposite to the head-end portion bone-facing surface and faces away from the bone, and disposed proximate to an edge of the head-end portion surface facing away from the bone (Specification -- pg. 12, lines 1-3; pg. 12, lines 24-31; Figs. 1A-1B; and wherein the at least one receiving member comprises a tube, an eyelet, a round hook, or a hole, each defining a substantially circular and circumferentially enclosed aperture through which wire cerclage or suture material may be inserted, threaded, or passed, the aperture having a central aperture axis disposed to extend substantially parallel to the head-end portion surface facing away from the bone, and to the edge of the head-end portion surface to which the receiving member is closest (Specification -- pg. 5, lines 11-18; pg. 7, lines 4-7; pg. 8, lines 1-3; pg. 9, lines 1-8; pg. 12, lines 24-29; pg. 13, lines 5-9; pg. 14, lines 10-14; Figs. 1A-1B).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claim 29 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,988,350 to Herzberg (hereinafter “Herzberg”).
2. Claim 29 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,409,489 to Sioufi (hereinafter “Sioufi”).
3. Claim 30 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Herzberg, and further over Sioufi.
4. Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Herzberg in view of U.S. Patent No. 4,454,876 to Mears (hereinafter “Mears”), and further over Sioufi in view of Mears.

VII. ARGUMENT

The contentions of the Appellant with respect to the ground of rejection presented for review, and the basis thereof, with citations of the statutes, regulations, authorities, and parts of the record relied upon are presented herein for consideration by the Board. Details as to why the rejections cannot be sustained are set forth below.

1. Section 102(b) rejection of claim 29 over Herzberg

Independent claim 29 was rejected under 35 U.S.C. § 102(b) as being anticipated by Herzberg. The standard for “anticipation” is one of fairly strict identity. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art of reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. Furthermore, anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, as arranged in the claim. *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Using these standards, Appellants submit the cited art fails to disclose each and every element of the currently pending claims, some distinctive features of which are set forth in more detail below.

Herzberg does not disclose a one-piece plate member. Present independent claim 29 describes a one-piece plate member. As well-known to a skilled artisan, a one-piece member is a monolithic member, not made up of two or more members fastened together in some fashion. It is further set out in claim 29 that the “shaft-end portion being narrower along a lateral direction than the head-end portion.” Clearly, claim 29 not only requires a narrower shaft-end portion than that of a head-end portion, but the overall plate member made up of the shaft-end portion and head-end portion must be a one-piece plate.

The Office Action mailed July 9, 2007 (“Final Office Action”) states that Herzberg discloses an implant plate comprising a head-end portion 25a and a shaft-end portion 24 (Final Office Action -- pg. 2). While region 25a of Herzberg is near the head region, opposite the shaft-

end 24, one must keep in mind that region 25 (alleged head-end portion) must be wider than the shaft-end portion. Thus, the head-end portion of Herzberg must include the wider circumferential edge 125 that is secured to region 25a (Herzberg -- Figs. 2, 3, etc.). However, it is clear that in order to formulate a plate member having a wider head-end portion and a narrower shaft-end portion, that plate 20 of Herzberg can no longer be a one-piece plate, but must have portion 125 secured to region 25.

Herzberg does not disclose a plate member having a substantially uniform thickness of 0.5 to 6.5 mm. Present independent claim 29 specifically describes the thickness of the plate member. That thickness can vary, but is preferably between 0.5 to 6.5 mm.

Contrary to the presently claimed thickness, nowhere is there any mention in Herzberg of the desired thickness of section 24, 25, edge 125, or any portions of plate 20. The Final Office Action contends that this limitation is a functional limitation. Appellants respectfully disagree. It is clearly described in claim 29 that the plate member “is a one-piece plate . . . having a substantially uniform thickness of 0.5 to 6.5 mm.” The qualifier or modifier that describes the thickness of the claimed one-piece plate is clearly part and parcel to the overall claimed apparatus.

Herzberg does not disclose a receiving member disposed on a head-end portion surface opposite the head-end portion, bone-facing surface. Present independent claim 29 describes a plate member having both a head-end portion and a shaft-end portion. The head-end portion has a bone-facing surface and a surface opposite the bone-facing surface. The same applies for the shaft-end portion. Claim 29 also describes a “receiving member . . . disposed on a head-end portion surface which is opposite to the head-end portion bone-facing surface.” When examining the claimed receiving member, one must keep in mind that the receiving member of claim 29 is one defined as having a “substantially circular and circumferentially enclosed aperture.”

Contrary to the configuration of claim 29, the only receiving members described in Herzberg are slot-shaped cutouts 129 extending from a surface of the head region 25a opposite the head-end bone facing surface. However, a slot or cutout as shown does not in any fashion describe a substantially circular and circumferentially enclosed aperture as claimed.

Herzberg does not disclose a receiving member comprising a tube, an eyelet, a round hook, or a hole, each defining a substantially circular and circumferentially enclosed aperture, and having a central axis disposed substantially parallel to the head-end portion surface and to the edge of the head-end portion surface. Present independent claim 29 not only defines the receiving member as having a substantially circular and circumferentially enclosed aperture, but also the aperture having a central axis that extends parallel to the head-end portion surface opposite the bone facing surface, and parallel to the edge of the head-end portion surface to which the receiving member is closest.

Even if the slot-shaped cutouts 129 in Herzberg were magically formed as having a circumferentially enclosed aperture, they would nonetheless have a central axis that is not parallel to the edge of the head-end portion 25a to which the slots 129 are closest. In fact, the central axis of slot 129 (if a tube, eyelet, a round hook, or a hole is formed) would extend perpendicular to the edge of head-end portion 25a, not parallel.

For at least the aforesaid reasons, Appellants assert that the rejection of independent claim 29 as to Herzberg cannot be sustained.

2. Section 103(a) rejection of claim 29 over Sioufi

Independent claim 29 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sioufi. To establish a case of *prima facie* obviousness of a claimed invention, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Second, there must be a reasonable expectation of success. As stated in MPEP 2143.01, the fact that references can be hypothetically combined or modified is not sufficient to establish a *prima facie*

case of obviousness. See *In re Mills*, 916 F.2d. 680 (Fed. Cir. 1990). Finally, the prior art references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d. 981 (CCPA 1974); MPEP 2143.03. Specifically, “all words in a claim must be considered when judging the patentability of that claim against the prior art.” *In re Wilson* 424 F.2d., 1382 (CCPA 1970).

Moreover, in response to the recent U.S. Supreme Court decision in *KSR Int’l Co. v. Teleflex, Inc.* (U.S. 2007), new guidelines were set forth for examining obviousness under 35 U.S.C. § 103. The U.S. Supreme Court reaffirmed the *Graham* factors and, while not totally rejecting the “teachings, suggestion, or motivation” test, the Court appears to now require higher scrutiny on the part of the U.S. Patent & Trademark Office. In accordance with the recently submitted guidelines, it is “now necessary to identify the reason” why a person of ordinary skill in the art would have combined or modified the prior art elements, or at least describe the pertinence of the prior art elements set forth in the cited disclosure, in the manner presently claimed. Moreover, even if combined or modified, the *Graham* factors require that a determination of the differences between the combined prior art and the claims at issue is needed. Using these standards, Appellants contend that the Final Office Action fails to identify the reasons for modifying or combining the cited references and, even if combined or modified, fails to note substantial differences between the combined references and the claims at issue. Some distinctive features of the presently pending claims are set forth in more detail below.

Sioufi does not teach or suggest, and no reasons were identified as to why a skilled artisan would derive from Sioufi, a one-piece plate member. As described above, claim 29 sets forth a one-piece member defined and known clearly as a monolithic member. Miriam-Webster’s Dictionary, 10th Edition.

Contrary to claim 29, Sioufi describes a compression plate 73. While it appears from Fig. 8a in Sioufi that compression plate 73 does not comprise a head-portion made up of items 82 and 77 that is greater along a lateral direction than the shaft-end portion as claimed, Appellants nonetheless can make the assumption that the head-end portion can somehow be enlarged. If enlarged in a manner in which the lateral direction of the shaft-end portion is narrower than the lateral direction of the head-end portion as claimed, then the head-end portion

of Sioufi must constitute both blades 77 and barrel 82. Nowhere does Sioufi suggest the benefit of enlarging the head-end portion relative to the shaft of compression plate 73, nor does Sioufi suggest a desirability to form blades 77 and barrel 82 as a one-piece monolithic structure with the shaft-end portion. At a minimum, there must be some teaching or suggestion within Sioufi or explicit reasoning given as to why a skilled artisan would modify Sioufi given its teachings to arrive at the limitations of claim 29.

Sioufi does not teach or suggest, and no reasons were identified as to why a skilled artisan would derive from Sioufi, a plate member having a substantially uniform thickness of 0.5 to 6.5 mm. As discussed above, claim 29 describes a specific thickness of the plate member as being between 0.5 and 6.5 mm.

Contrary to the claimed thickness, there is no description in Sioufi of the thickness of compression plate 73 or any of the other various items needed for the mounting kit, or for securing plate 73 to bone. Absent any suggestion of a desired thickness, a skilled artisan would derive that the desired thickness must be much greater than that presently claimed. As stated throughout Sioufi, the apparatus, kit, compression plate, or any other apparatus specifically targeted for an application which requires additional thickness -- that application being for a femur, femoral head, or human hip. The weight-bearing forces on the femoral head, neck, or hip area are substantially greater than the upper arm head and upper arm bone. Thus, a skilled artisan would know to substantially increase the thickness of the leg and hip region of the securing plate member in Sioufi (or Herzberg) beyond that which is presently claimed.

Sioufi does not teach or suggest, and no reasons were identified as to why a skilled artisan would derive from Sioufi, a receiving member disposed on a head-end portion surface opposite the head-end portion, bone-facing surface. As discussed above, claim 29 describes receiving member 26 being disposed on head-end portion 2 and, specifically, on a surface of head-end portion 2 opposite a bone-facing surface (Specification -- Figs. 1A-1B).

Contrary to claim 29, Sioufi describes eyelets 88 (Sioufi -- Figs. 8a-8b). Eyelets 88 are clearly shown to extend perpendicularly outward from a surface, but certainly not a surface opposite a bone-facing surface. Moreover, the surface from which eyelets 88 extend are not the head-end portion, but the shaft-end portion -- the head-end portion being portions 82 and 77 (Sioufi -- Figs. 8a-8b). Thus, Sioufi shows eyelets 88 not extending from the head portion nor from the surface of the head portion opposite that which bears against bone. Instead, eyelets 88 in Sioufi extend from the lateral surface of the shaft region of compression plate 77. The reason for this configuration is due to the requirements of Sioufi -- eyelets 88 must extend from the lateral extents or side surfaces of the shaft region because the eyelets are dimensioned to receive the threaded screws 99 of hook member 93 (Sioufi -- Fig. 9). Hook member 93 extends around the femoral bone and, more specifically, the proximal femur D (Sioufi -- Fig. 1). When placed, plate 101 bears against the surface of the femur and on the opposite surface of the femur is plate 73. Eyelets 88 receive threads 99 so that the bone is secured between coupling plate 101 and compression plate 73.

In order to effectuate the coupling of hook member 93, it is required that eyelets 88 extend from the lateral surface of the shaft portion of compression plate 73 -- not the claimed head portion or head portion surface opposite the head portion surface that abuts against bone. If Sioufi were modified so that eyelets 88 are relocated to extend from the head portion (with no suggestion in Sioufi to do so), then it would be impossible for hook 93 and rigid threads 99 to have access to eyelets 88 since access is mandated from the opposite side of the femoral bone. Therefore, the proper test in determining obviousness given the teachings of Sioufi is to examine Sioufi through a person skilled in the art to determine if Sioufi can be modified. If, however, the proposed modification would change the principle of operation of Sioufi or render the securement of the threaded screws 99 infeasible or unsatisfactory for its intended purpose, then it would be proper to disregard Sioufi as a reference that would render the claims unpatentable. *See, In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); *In re Ratti*, 270 F.2d 910 (CCPA 1959); MPEP 2143.01.

Sioufi does not teach or suggest, and no reasons were identified as to why a skilled artisan would derive from Sioufi, a receiving member comprising a tube, an eyelet, a round hook, or a hole, each defining a substantially circular and circumferentially enclosed aperture, and having a central axis disposed substantially parallel to the head-end portion surface and to the edge of the head-end portion surface. As discussed above, claim 29 not only describes a receiving member with an aperture having a central axis that extends parallel to the surface of the head-end portion facing away from bone, but also describes the central axis being parallel to the edge of the head-end portion to which the receiving member is closest. For example, if one were to examine present Figs. 1A-1B, aperture 7 of receiving member 6 includes a central axis (shown by a shortened line through aperture 7). The shortened line (or axis) of at least one aperture 7 of at least one receiving member 6 is shown to be parallel not only to the surface of the head-end portion 2 opposite that which bears against bone, but also parallel to the lateral extent of the head-end portion 2 to which the receiving member 6 is closest. For example, the lateral extent closest to receiving member 6 is that that extent or edge to which the axis is parallel.

Contrary to claim 29, instead of the aperture of eyelets 88 in Sioufi forming a central axis parallel to the edge of the head-end portion, a central axis of eyelets 88 extends perpendicular to the lateral extents and, more specifically, a line which forms the lateral extents of the first and second head sides (Sioufi -- Fig. 8a). Yet further, the central axis of eyelets 88 clearly do not extend substantially parallel to the head-end portion surface. To do so would require that the head-end portion made up of member 82 be bent perpendicular to the shaft-end portion so that the central axis of eyelets 88 would extend along the perpendicularly-bent surface and the corresponding lateral extents. Neither Figs. 8a, 8b, nor the written description of Sioufi make any mention of bending the head-end portion perpendicular, or suggest a desirability to do so. Appellants appreciate the careful drawing on page 6 of the Office Action Mailed January 17, 2007 depicting Fig. 8b of Sioufi. Appellants nonetheless note that the central axis of the drawn receiving member/eyelet 88 is not parallel to the edge of the head-end portion to which the receiving member is closest, nor is the central axis parallel to the surface of the head-end portion opposite the bone-facing surface.

For at least the aforesaid reasons, Appellants assert that the rejection of independent claim 29 as to Sioufi cannot be sustained.

3. Section 103(a) rejection of claim 30 over Herzberg or Sioufi

Dependent claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Herzberg or Sioufi. It is asserted that dependent claim 30 is patentable over both Herzberg and Sioufi for at least the same reasons as base claim 29 discussed above.

4. Section 103(a) rejection of claim 31 over the combination of Herzberg and Mears or the combination of Sioufi and Mears

Dependent claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Herzberg and Mears or the combination of Sioufi and Mears. It is asserted that dependent claim 31 is patentable over both Herzberg and Sioufi in combination with Mears for at least the same reasons as base claim 29 discussed above.

* * *

For the foregoing reasons, it is submitted that the Examiner's rejection claims 29-31 was erroneous, and reversal of the Examiner's decision is respectfully requested. Moreover, Appellant respectfully requests that, upon allowance of a generic claim (e.g., claim 29), the claims directed at non-elected species (i.e., claims 17-19, 21, and 22) be allowed under 37 C.F.R. § 1.141(a).

The Commissioner is hereby authorized to charge the required fee(s) or credit any overpayment to Daffer McDaniel, LLP deposit account number 50-3268.

Respectfully submitted,

/Kevin L. Daffer/

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Date: December 6, 2007

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VIII. APPENDIX

The present claims on appeal are as follows.

29. Implant plate for stabilizing a fracture of at least one of an upper arm head or a proximal upper arm, comprising:

a plate member shaped to bear against a surface of an upper arm head bone and a surface of a proximal upper arm bone;

holes for bone screws on the plate member for fixing the plate member to the bone surfaces;

at least one receiving member for flexible cerclage wires or suture material wound around fractured bone parts, allowing a passage and tightening of the wire cerclage or suture material after the plate member has been secured to the bone surfaces;

wherein the plate member is a one-piece plate cut or punched from a flat metallic strip material having a substantially uniform thickness of 0.5 to 6.5 mm to have plate edges defining a head-end portion and a shaft-end portion adjacent to the head-end portion along a longitudinal direction, with the shaft-end portion being narrower along a lateral direction than the head-end portion, and bent to have a slight curvature to form a longitudinal channel, and to allow a bone-facing surface of the head-end portion and a bone-facing surface of the shaft-end portion to bear against the outer surfaces of the upper arm head bone and the proximal upper arm bone;

wherein the holes for bone screws are located on the head-end portion and the shaft-end portion;

wherein the at least one wire cerclage or suture material receiving member is disposed on a head-end portion surface which is opposite to the head-end portion bone-facing surface and faces away from the bone, and disposed proximate to an edge of the head-end portion surface facing away from the bone; and

wherein the at least one receiving member comprises a tube, an eyelet, a round ~~hood~~ hook, or a hole, each defining a substantially circular and circumferentially enclosed aperture through which wire cerclage or suture material may be inserted, threaded, or passed, the aperture having a central aperture axis disposed to extend substantially parallel to the head-end portion surface facing away from the bone, and to the edge of the head-end portion surface to which the receiving member is closest.

30. Implate plate according to claim 29, wherein the thickness of material of the plate member is 0.8 to 3.5 mm.

31. Implate plate according to claim 29, wherein the plate member is of implant steel, titanium, or a titanium alloy.

IX. EVIDENCE APPENDIX

No evidence has been entered during the prosecution of the captioned case.

X. RELATED PROCEEDINGS APPENDIX

No prior or pending appeals, interferences, or judicial proceedings are known to Appellant or Assignee which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.